MAY 3 0 2012

510(k) Summary
21 CFR 807.92

Site~Rite Prevue* Ultrasound System, Pinpoint* Gel Cap and Pinpoint* Needle Guide

General Provisions	Submitter Name: Submitter Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Kerrie Hamblin Senior Regulatory Affairs Specialist Bard Access Systems, Inc. kerrie.hamblin@crbard.com 801.522.5000 ext 4909 801.522.5425 fax
	Date of Preparation:	17 May 2012
Subject Device	Trade Name:	**Site~Rite Prevue* Ultrasound System**
	Classification Name:	IYO 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducers Class II, Radiology
Predicate Devices	Trade Name:	Site~Rite Vision* Ultrasound System
	Classification Name:	IYN 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System IYO 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducers LLZ 21 CFR 892.2050 Picture Archiving and Communications System
	Premarket Notification:	K100402, concurrence date 05 March 2010
	Manufacturer:	Bard Access Systems, Inc.
	Trade Name:	Site~Rite* 6 Ultrasound System
	Classification Name:	IYO 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducers
	Premarket Notification:	K071204, concurrence date 18 May 2007
	Manufacturer:	Bard Access Systems, Inc.
Subject Device	Trade Name:	**Pinpoint* Gel Cap**
	Classification Name:	MUI 21 CFR 892.1570 Diagnostic Ultrasonic Transducer Class II, Radiology

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Predicate Devices	Trade Name:	Embrace™ Gel Pad
	Classification Name:	MUI 21 CFR 892.1570 Diagnostic Ultrasonic Transducer
	Premarket Notification:	K072515, concurrence date 20 September 2007
	Manufacturer:	Orison Corporation
	Trade Name:	ScanTac™ Pad
	Classification Name:	MUI 21 CFR 892.1570 Diagnostic Ultrasonic Transducers
	Premarket Notification:	K031894, concurrence date 18 July 2003
	Manufacturer:	SONOTECH, Inc.
Subject Device	Trade Name:	**Pinpoint* Needle Guide**
	Classification Name:	ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducer Class II, Radiology
Predicate Device	Trade Name:	Site~Rite* Needle Guide Kits and Site~Rite* Probe Cover Kit
	Classification Name:	ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducers
	Premarket Notification:	K042445, concurrence date 19 October 2004
	Manufacturer:	Bard Access Systems, Inc.

Device Description - Site~Rite Prevue* Ultrasound System	The **Site~Rite Prevue* Ultrasound System** is a portable device that features real-time 2D ultrasound imaging. Additional features include compact size, simple user interface, and various calculations. The system may incorporate various accessories, including an upright stand, A/C adapter, needle guide/gel cap kits, etc. The system includes USB support for storage devices with no external power connections (e.g., USB flash drive).
Device Description - Pinpoint* Gel Cap	Bard Access Systems, Inc.'s, **Pinpoint* Gel Cap** is a sterile, single use accessory for use with the **Site~Rite Prevue* Ultrasound System**. The device is intended for use as an ultrasound coupling medium. This device attaches to the ultrasound transducer and contains a hydrogel pad that interfaces directly with the transducer face and the patient's skin to provide an acoustic coupling pathway. The device contains a feature that accommodates attachment of the **Pinpoint* Needle Guide**. A removable lid protects the hydrogel pad during transit and while the clinician is attaching the device on the **Site~Rite Prevue*** ultrasound transducer.
Device Description - Pinpoint* Needle Guide	The **Pinpoint* Needle Guide** is a sterile, single use accessory for use with ultrasound. The device is intended to provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of the needle in a specific structure. The **Pinpoint* Needle Guide** attaches to the **Pinpoint* Gel Cap** which attaches to the ultrasound probe. Each needle guide accommodates multiple vein depths.

Indications for Use / Intended Use - Site~Rite Prevue* Ultrasound System, Pinpoint* Gel Cap and Pinpoint* Needle Guide	The **Site~Rite Prevue* Ultrasound System** is intended to provide ultrasound imaging of the human body. Specific clinical applications include: • Adult Cephalic • Neonatal Cephalic • Pediatric • Peripheral Vessel The gel cap is intended for use as an ultrasound coupling medium for use with the **Site~Rite Prevue* Ultrasound System**. The device is intended for use with pediatrics and adults. The needle guides are intended to provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure. This device is intended for use with pediatrics and adults.
Technological Characteristics	Technological characteristics of the subject **Site~Rite Prevue* Ultrasound System, Pinpoint* Gel Cap** and **Pinpoint* Needle Guide** are equivalent with respect to the basic design and function to that of the predicate devices, Site~Rite Vision* Ultrasound System, Site~Rite* 6 Ultrasound System, Embrace™ Gel Pad, ScanTac™ Pad, and Site~Rite* Needle Guide Kits and Site~Rite* Probe Cover Kit respectively.
Safety & Performance Tests	Verification and validation activities were designed and performed to demonstrate that the subject **Site~Rite Prevue* Ultrasound System, Pinpoint* Gel Cap** and **Pinpoint* Needle Guide** met predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

IEC 60601-1:1988/1991/1995	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
IEC 60601-1-2:2007	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-2-37:2008	Medical Electrical Equipment - Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
NEMA UD 2:2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
ISO 10993-1:2009	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
ISO 11607-1:2006	Packaging for Terminally Sterilized Medical Devices
ISO 11607-2:2006	Packaging for Terminally Sterilized Medical Devices
ISO 11137-1:2006/(R) 2010	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
ISO 11137-2:2006	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

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ISO 11137-3:2006/(R)2010	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspect

The subject devices met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate devices.

Non-Clinical Comparative Testing

Summary of Acoustic Testing (mean values)

Test Characteristic	Pinpoint* Gel Cap	Aquasonic 100 Ultrasound Trans. Gel
Sound Velocity (m/s)	1502	1558
Acoustic Impedance (MRayls)	1.526	1.641
Attenuation 5 MHz (dB/(cm MHz))	0.0657	0.0792

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Site~Rite Prevue* Ultrasound System, Pinpoint* Gel Cap** and **Pinpoint* Needle Guide**, met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate devices, Site~Rite Vision* Ultrasound System, Site~Rite* 6 Ultrasound System, Embrace™ Gel Pad, ScanTac™ Pad, and Site~Rite* Needle Guide Kits and Site~ Rite* Probe Cover Kits respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

CR Bard, Inc.
% Mr. Mark Job
Owner/Reviewer
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

MAY 30 2012

Re: K120882
Trade/Device Name: Site~Rite Prevue*, Pinpoint* Gel Cap and Pinpoint* Needle Guide
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: May 17, 2012
Received: May 18, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120882

Device Names: **Site~Rite Prevue*, Pinpoint* Gel Cap and Pinpoint* Needle Guide**

Indications for Use:

The Site~Rite Prevue* Ultrasound System is intended to provide ultrasound imaging of the human body. Specific clinical applications include:

- **Adult Cephalic**
- **Neonatal Cephalic**
- **Pediatric**
- **Peripheral Vessel**

The gel cap is intended for use as an ultrasound coupling medium for use with the Site~Rite Prevue* Ultrasound System. The device is intended for use with pediatrics and adults.

The needle guides are intended to provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure. This device is intended for use with pediatrics and adults.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120882

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Diagnostic Ultrasound Indications for Use Form - *Site~Rite Prevue* Ultrasound System*

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (abdominal, thoracic, and vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)							
	Neonatal Cephalic	N						
	Adult Cephalic	N						
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-Esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N						
	Other (Specify)							

N = new indication; **P** = previously cleared by FDA; **E** = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120882

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